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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,088	01/18/2002	Graham John Hamilton Melrose	2354/141 (FF34527/02)	6479

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EXAMINER
KUMAR, PREETI

ART UNIT	PAPER NUMBER
1751	7

DATE MAILED: 08/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/053,088	MELROSE ET AL.	
	Examiner	Art Unit	
	Preeti Kumar	1751	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Non-Final Rejection

1. Claims 1-43 are pending.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, claim 1 is generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical

Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1-9 and 12-23 and 43 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Melrose et al. (US 6,410,040).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome

either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Melrose et al. teach a method for the preparation of compositions of poly(2-propenal, 2-propenoic acid) comprising the method steps of dissolving the poly(2-propenal, 2-propenoic acid) in aqueous base, adding an organic compound containing one or more hydrophobic groups, and subsequently acidifying the solution, whereby interaction between the hydrophobic groups of the organic compound and the poly(2-propenal, 2-propenoic acid) prevents precipitation of the poly(2-propenal, 2-propenoic acid) occurring at pH >5.5 and the solution is consequently stable over a broad pH range. See abstract. Specifically, Melrose et al. teach polymeric compounds having a polyacrolein sub-unit in aldehyde, hydrated, hemi-acetal or acetal form and having biostatic or biocidal properties and the biostatic and/or biocidal uses of these compositions. See col.1, ln.5-12.

Melrose et al. teach that antimicrobial compositions may be used as preservatives, or as the active ingredients in disinfectants, dermatological compositions including sun screen formulations or antiseptic formulations, or in animal feed additives. Generally these antimicrobial compositions must: be stable; be efficacious in killing micro-organisms within a specified time; be safe, that is be reasonably free of toxicity which may be caused by the trans-dermal migration of low molecular weight ingredients into the blood-stream so as to manifest toxicity, antigenicity, allergy, irritation or inflammation; have minimal odour; and in some dermatological preparations, have the

property of sun screening and minimise adverse dermatological effects from the generation of free-radicals. See col.1, ln.60 – col.2, ln.10.

Specifically regarding claims 12-22, Melrose et al. teach that the composition further comprises one or more of ethylene diamine tetra acetic acid, a lower alkanol, a phenol, isothiazolinones and glutaraldehyde, whereby the composition exhibits a synergistic increase in antimicrobial activity. See col.3 in its entirety and example 7.

Regarding claims 5-9, 23 and 43, Melrose et al. illustrate in example 8 the effects of the presence of poly(2-propenal, 2-propenoic acid) on the migration of various agents across a model for skin wherein (a) poly(2-propenal, 2-propenoic acid) (0.5 g) was dissolved in polyethylene glycol 1000 (10 g) by stirring at 70.degree. C., then sodium hydroxide micro-pellets (50 mg) were added and stirred for 2 minutes, and then octyl methoxy cinnimate (10 g; sunscreen agent) was added, followed by a mixture of the polymeric emulsifiers PEMULIN TR1 and CARBOPOL 2984 (0.5 g; equal parts) whilst maintaining the temperature at 70.degree. C./15 minutes. See col.11. Accordingly, the broad teachings of Melrose et al. appear to anticipate the material limitations of the instant claims.

Alternatively, even if the broad teachings of Melrose et al. are not sufficient to anticipate the material limitations of the instant claims, it would have been nonetheless obvious to one of ordinary skill in the art, to arrive at an antimicrobial composition comprising the specified amounts of antimicrobial as recited by the instant claims because Melrose et al. teach poly(2-propenal, 2-propenoic acid) which are useful preservatives, or as the active ingredients in disinfectants, dermatological compositions

including sun screen formulations or antiseptic formulations, or in animal feed additives meeting regulatory standards.

8. Claims 24-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Melrose et al. (US 6,410,040).

Melrose et al. are relied upon as set forth above. However, Melrose et al. do not specifically teach a method of treating gastrointestinal disease in an animal with compositions of poly(2-propenal, 2-propenoic acid) and the specified dosages for administration as recited by the instant claims.

However, Melrose et al. illustrate by example microbiological test of poly(2-propenal, 2-propenoic acid) with various organisms such as P. vulgaris, E. coli, Ps. Aeruginosa. See Table 10A.

Thus, one of ordinary skill in the art would have been motivated to use a composition comprising poly(2-propenal, 2-propenoic acid) in a method of treating gastrointestinal disease in animals because Melrose et al. suggest the use of poly(2-propenal, 2-propenoic acid) as an antimicrobial agent against various organisms such as P. vulgaris, E. coli, Ps. Aeruginosa which are known to cause gastrointestinal disease in animals.

9. Claims 1-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Manoury et al. (US 4,711,892).

Manoury et al. teach 5-nitro-2-furyl derivatives of pyridylpropenoic acid hydrazides which are useful in treating bacterial, fungal, protozoal, parasitic and intestinal infections. See abstract. Manoury et al. teach a compound of formula (III)

wherein m is 0 is 5-nitrofuran-2-carbaldehyde and can be produced by known methods. The compound of formula (III) wherein m is 1 is 3-(5-nitro-2-furyl)-2-propenal and this is prepared by an aldolization reaction between 5-nitrofuran-2-carbaldehyde and acetaldehyde followed by purification by chromatography on a silica column. The hydrazides of formula (II) can be prepared by reaction between the corresponding ethylenic acids and dry hydrazine in the presence of condensation agents (such as, for example, dicyclohexylcarbodiimide, EEDQ, and the like), or alternatively by reaction between hydrazine and an activated derivative of the corresponding ethylenic acid (such as, for example, a mixed anhydride, an imidazolide, and the like). The ethylenic acids are prepared from corresponding aldehydes by condensation with ester or acid derivatives having an activated methylene group. See col.1. In example I Manoury et al. illustrate preparation of ethylenic acids. See col.2. Manuory et al. teach that the compounds of the invention can be used clinically in man at doses of 20 mg to 1 g/day, the unit dosage being between 5 and 200 mg; the compounds can be used in animals at doses of 1 to 20 mg/kg/day. The compounds can be presented in any suitable form for oral, rectal or patenteral administration, for example in the form of capsules, tablets, granules, gelatin capsules or liquid solutions, or syrups or suspensions to be taken by mouth, and can contain the appropriate excipients. The compounds can be used in animals and man as antibacterials, intestinal antiseptics, antifungals and/or antiprotozoals. In particular, in man they may be employed to treat infectious functional colopathies, diarrhoea of alimentary or other origin, enteritis, enterocolitis and bacillary dysenteries. The compounds can also be used for protection and preservation of

foodstuffs, and to promote the growth of livestock by controlling bacterial and parasitic infections. Accordingly Manoury et al. teach compounds of formula (I) as hereinbefore defined for use in a method of treatment of the human or animal body by therapy or a method of surgery or diagnosis practiced in the human or animal body. And furthermore, Manoury et al. teach a pharmaceutical composition comprising a compound of formula (I) and an inert carrier or diluent therefore. Such compositions may be in unit- or multi-dosage form. See col.1-2 and examples 1-2. Accordingly, the broad teachings of Manoury et al. appear to anticipate the material limitations of the instant claims.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1-43 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 of U.S. Patent No. 6,410,040. Although the conflicting claims are not identical, they are not patentably

distinct from each other because claims 1-28 of US 6,410,040 encompass the material limitations of the instant claims.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Remaining references cited but not relied upon are considered to be cumulative to or less pertinent than those relied upon or discussed above. Applicant is reminded that any evidence to be presented in accordance with 37 CFR 1.131 or 1.132 should be submitted before final rejection in order to be considered timely.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Preeti Kumar whose telephone number is 703-305-0178. The examiner can normally be reached on M-F 9:00am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yogendra Gupta can be reached on 703-308-4708. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-872-9309.

Preeti Kumar
Examiner
Art Unit 1751

YOGENDRA N. GUPTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700

PK
August 8, 2003